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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,862	03/14/2006	Charlotte Ip	21519P	6964

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EXAMINER	
KIM, YOUNG J	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
02/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,862	IP, CHARLOTTE	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

No IDS has been filed to date of the present communication.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because while the claim recites that it is drawn to a real time qPCR assay, the method does not have any active steps for conducting said method.

Claims 2-6 are indefinite by way of their dependency on claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al. (Virology, 1995, vol. 207, no. 1, pages 327-333).

The transitional phrase, "having" is interpreted as being open, such as the transitional phrase, "comprising."

Rao et al. disclose a nucleic acid sequence comprising all of the sequences of instant SEQ ID Number 2 (see below), thereby clearly anticipating the invention as claimed.

```
  Query Match             100.0%;  Score 33;  DB 10;  Length 1041;
  Best Local Similarity   100.0%;  Pred. No. 0.0025;
  Matches   33;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ATGAGCACAATAGTTAAAAGCTAACACTGTCAA 33
              |||||||||||||||||||||||||||||||||
Db        976 ATGAGCACAATAGTTAAAAGCTAACACTGTCAA 1008
```

Rao et al. also disclose a nucleic acid sequence comprising all of the sequences of instant SEQ ID Number 3 (see below), thereby clearly anticipating the invention as claimed.

```
  Query Match             100.0%;  Score 20;  DB 10;  Length 1049;
  Best Local Similarity   100.0%;  Pred. No. 14;
  Matches   20;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ACCATCTACACATGACCCTC 20
              ||||||||||||||||||||
Db        963 ACCATCTACACATGACCCTC 982
```

Therefore, Rao et al. anticipate the invention as claimed.

Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Buonagurio et al. (US 2005/0119471 A1, published June 2, 2005, filed February 19, 2003, priority, February 27, 2002).

Buonagurio et al. disclose a nucleic acid sequence, SEQ ID Number 42, which shows a 100% sequence identity to SEQ ID Number 4 (see below), thereby clearly anticipating the invention as claimed.

```
  Query Match             100.0%;  Score 16;  DB 11;  Length 22;
  Best Local Similarity   100.0%;  Pred. No. 85;
  Matches   16;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 GGTCACATAACGCCCC 16
              ||||||||||||||||
Db          1 GGTCACATAACGCCCC 16
```

Therefore, the invention as claimed is clearly anticipated by Buonagurio et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. (Virology, 1995, vol. 207, no. 1, pages 327-333) in view of Aoyagi et al. (U.S. Patent No. 5,952,202, issued September 14, 1999) and Buck et al. (BioTechniques, September 1999, vol. 27, pages 528-536).

The teachings of Rao et al. with regard to SEQ ID Numbers 2 and 3 have already been discussed above.

With regard to SEQ ID Number 4, Rao et al. disclose a nucleic acid sequence comprising <u>all</u> of the sequences of instant SEQ ID Number 4 (see below).

```
  Query Match             100.0%;  Score 16;  DB 10;  Length 1041;
  Best Local Similarity   100.0%;  Pred. No. 47;
  Matches   16;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 GGTCACATAACGCCCC 16
              ||||||||||||||||
Db       1041 GGTCACATAACGCCCC 1026
```

Rao et al. do not explicitly disclose the primers consisting of SEQ ID Number 3 and 4, and a confirmation primer consisting of SEQ ID Number 2, nor do the artisans employ a real time qPCR method in their assay involving a confirmation primer comprising a FET label.

Aoyagi et al. disclose an efficient method of detecting target nucleic acids via use of a quantitative PCR method, wherein the artisans employ an oligonucleotide probe comprising a donor label and quencher label at its respective ends (Figure 1; column 10, lines 51-61).

With regard to claims 3 and 10, the Aoyagi et al. explicitly disclose that the reporter dye is attached at 5' terminus or 3' terminus of the probe and that the quencher dye is attached at the 5' terminus or the 3' terminus of the probe (column 8, lines 56-62), said label being FAM (column 9, lines 27-28) or TAMRA (column 9, line 35).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Rao et al. and Ayogi et al., thereby arriving at the invention as claimed for the following reasons.

While Rao et al. provides the motivation to detect the presence of Rotavirus, the artisans employ a traditional method of amplification method and cloning.

Given the advantage offered by Ayogi et al., which allows the real-time amplification and detection of target nucleic acids in a sample, one of ordinary skill in the art would have been clearly motivated to combine the teaching of Ayogi et al. with the teachings provided for by Rao et al., arriving at a real time amplification and detection method for rotavirus in a sample.

With regard to deriving the necessary primers from a known prior art target sequence is not deemed inventive as being well within the purview of an ordinarily skilled artisan.

As demonstrated above, all of the instantly claimed primers were derived from a prior art rotavirus sequence, as evidenced by the teachings of Rao et al. who showed that every single primer had 100% identity (in its entirety) to various regions of prior art rotavirus sequence.

Buck provides evidence of the equivalents of primers. Specifically Buck invited primer submissions from a number of labs (39) (page 532, 3rd column), with 69 different primers being

submitted (see page 530, 1st column). Buck also test 95 primers spaced at 3 nucleotide intervals along the entire sequence (known) at issue, thereby testing more than 1/3 of all possible 18-mer primers on the 300 base pair sequence (see page 530, 1st column). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, 1st column). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, 1st column). Buck expressly states, "the results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (see page 535, 2nd column)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however, different, used by different 39 laboratories. It is particularly striking that all 95 control primers functioned which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

In addition, in *In re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologous, however, the court stated:

"Normally a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationship may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologues because homologues often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

Since the primers employed by the instant claims simply represent functional homologues of the prior art rotavirus sequence (as evidenced by Rao et al., absent secondary consideration, one of ordinary skill in the art would have been able to design such primer sets in view of the fact that there exists computerized programs which allow one of ordinary skill in the art to design the optimal primers for such purpose, rendering the claims *prima facie* obvious over the cited references.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the

status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/
Primary Examiner, Art Unit 1637
2/25/2008

/YJK/